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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,240	06/30/2000	Matthew Joseph Doyle	8147	8182

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/607,240	DOYLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ralph Gitomer	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

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The amendment received 9/9/05 has been entered and claims 5-18 are currently pending in this application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some agents such as flavors, does not reasonably provide enablement for "an additional therapeutic agent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that the generic disclosure of additional therapeutic agents supplies sufficient written description.

It is the examiner's position that one of skill in this art would not know what is included or excluded by the terms.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition to the claims of the limitation "in the absence of an H2 antagonist" is new matter. The specification as originally filed teaches on page 15 line 5 and page 31 first paragraph, various H2 antagonists that may be included in the composition. Present claim 7 requires inclusion of an H2 antagonist. A negative limitation such as excluding a component requires definitive written description which is not found in the specification.

During prosecution of this application, claims 10-12 were amended to require that the composition not include H2 antagonists. In making this amendment, applicant did not point out where the original disclosure of this application describes this concept. Rather, it appears to have been inserted in an attempt to distinguish the invention from the Singer reference which includes H2 antagonists. We have reviewed the original disclosure of this application and do not find that it reasonably conveys the concept now claimed, i.e., that the present process is performed without the use of H2 antagonists. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); In re Winkhaus, 527 F.2d 637, 188 USPQ 129 (CCPA 1975).

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that the generic disclosure of additional therapeutic agents supplies sufficient written description for excluding H2 antagonists, a species within the genus of therapeutic agents.

It is the examiner's position that the specification provides no written description for the claimed concept of excluding H2 antagonists.

Claims 5-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims include Markush groups of antimicrobial agents, forms of the product, and H2 antagonists. And the function of this composition is to promote whole body health in human and other animals. Further, an additional therapeutic agent can be included. The specification as originally filed does not teach one of skill in this art how to make and use each and every of these components in each of the claimed forms. For example, how much of each component would be required in a chewing gum vs. a tooth gel? Which combinations would produce the desired results? No change in the health of any human or animal is seen in the specification as originally filed.

Claims 13-18 are directed to known health markers as indicators of health as regarding bacterial mediated systemic disease. The specification provides no nexus between any such claimed marker and prevention or treatment of bacterial periodontal infection in the oral cavity. The examiner is unaware of any of the claimed markers

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alone being a reliable indicator of the presence or absence of periodontal disease and are so generally claimed as to be meaningless, for example, "disregulation of glucose metabolism."

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that no undue experimentation would be required to make and use the therapeutic agents claimed. And as amended, the claims require an effective amount.

It is the examiner's position that independent claim 5 is directed to administering an antimicrobial agents where 22 different classes of such agents, their salts and mixtures and agents are claimed. No amounts, proportions, or combinations are set forth. And in claim 6 the composition can be in nine different forms. The specification does not teach one of skill in this art how to make and use such a composition for its stated function.

Claims 5-9 are rejected under 35 USC 102(b) as being anticipated by Singer as was decided by the Board of Appeals in the decision rendered 3/26/04.

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that Singer requires an H2 antagonist and optionally an antimicrobial agent. The present claims require an antimicrobial agent and optionally can include an H2 antagonist. The teachings of Singer do not inherently result in promotion of whole body health. The claims have been amended to require the antimicrobial agent to control bacterial infection.

It is the examiner's position that the presently claimed method is clearly taught by Singer and therefor anticipates the present claims. A reading of Singer would lead one to immediately envision a composition containing both an H2 antagonist as well as an antimicrobial agent.

Regarding the issue already decided by the Board of Appeals regarding the inherency of promoting whole body health, one practicing all the presently claimed method steps would inherently also promote whole body health. Now, considering the function of the presently claimed invention as promoting whole body health in more detail, promoting does not require accomplishing to a great degree where no degree is claimed, whole in context is undefined but may be considered to imply health beyond oral health alone. As such, the phrase is meaningless in context. For example, does taking a breath of air promote whole body health? Does drinking a sip of water promote whole body health? Does brushing one's teeth promote whole body health?

The nexus between oral health in general and brushing or otherwise cleaning teeth has been unassailable for centuries. So this discussion leaves us to decide whether there is any nexus to any degree between oral health in general and whole body health prior to 6/30/2000. It is the considered position of this examiner that due to

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the considerable percent of people whose death was caused by dental disease in pre-modern times which continues to this day in less developed populations, the nexus between serious illness, disability and death and dental disease would highly likely be well known. Further, it was well known at the time this invention was made that the health of carnivorous animals in the wild and in captivity is highly dependent upon their oral health. This examiner was witness to the deaths of many maned wolves in captivity due to periodontal disease that was resistant to treatment in the early 1980's. It would be likely that humans in contact with domesticated and wild animals would be well aware of the connection between oral infection, loss of teeth, loss of oral function and the attendant risk to health of the animals beyond these oral manifestations.

The teachings of Singer would inherently control bacterial infection and inhibit oral bacteria because Singer teaches applying the same composition to the same location. In the absence of any testing, the reduction in visible inflammation would be a standard indicator of reduction of infection where inflammation and infection have a common nexus. One would expect infection to produce inflammation in the oral cavity. Regarding Singer specifically, the title of Singer is "Use of H-2 Antagonists for Treatment of Gingivitis" and the abstract include prevention or treatment of gingivitis or periodontitis. Treating those who have and may be at risk for developing periodontal disease with antibacterial compounds as claimed is old in this art. See mouthwash ads from the past few decades.

The dose ranges presently claimed and taught by Singer overlap. No advantages are disclosed for the presently claimed dose ranges.



The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer.

The claims differ from Singer in that they exclude H2 antagonists in the composition.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to make oral care products containing other standard components as described by Singer with or without H2 antagonists because Singer describes specific functions of H2 antagonists for treating specific oral conditions and should one desire oral care products for other functions, one would not include H2 antagonists.

Oral care products not containing H2 antagonists were known at the time this invention was made. No particular function to H2 antagonists is presently claimed. Further, as a negative limitation to not include H2 antagonists, no advantage is seen. An undisclosed advantage is given little or no patentable weight.

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to encompass compositions that do not include an H2 antagonist and the amount of the composition are effective to promote whole body health. The compositions of Singer include H2 antagonists.

It is the examiner's position that Singer does not require including H2 antagonists in the compositions shown. Promoting whole body health is properly interpreted in a broad fashion and is encompassed by the teachings of Singer who teaches treating periodontal disease. The present claims read on administering to the oral cavity compositions containing antimicrobial agents in most any known form. No nexus between any method of treating and effectively treating periodontal disease, nor any nexus between treating periodontal disease and "whole body health" is claimed. An no novelty is seen in such a nexus.

Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer.

The claims differ from Singer in that they specify particular markers of body health.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ any known marker of body health as an indicator of body health because all the claimed markers are employed in this art in some fashion as markers of some dysfunction or disorder. None alone however are reliable markers of bacterial periodontal infection.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-18 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

The claims are directed to promoting whole body health in humans and other animals by administering the claimed composition containing a number of different permutations of a number of components. No evidence or examples are given for such a function in any human or any animal. Depending upon the interpretation of the phrase whole body health, the intended use is not specific, credible and substantial. No data is presented relating any of the claimed indices and bacterial periodontal infection.

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that the present invention is based on the discovery that periodontal infection stimulates a systemic response that can result in various diseases and conditions which are protected against by the claimed method. A Declaration by Offenbacher is presented which shows results of treating the mouse oral cavity with antimicrobial agents.

It is the examiner's position that the present claims are directed to treating humans specifically to promote whole body health by administering known antimicrobial agents. The claims read on preventing periodontal disease. The results of the Declaration are directed to treating periodontal infection which is not claimed. For example, a person who has end stage heart failure but nor oral infection would not likely to be said to have good whole body health. Would the presently claimed method promote whole body health in such a subject? And treating microbial infections in the oral cavity with known antimicrobial agents is not novel.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9, 13, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Dependent claim 7 should begin with a definite article. In claim 13 "inhibition of the bacteria" lacks antecedent basis. In claim 13 "indicted" is queried. In claim 18 line 2, "its" is confusing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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